

MAY 10 2001

## 510(k) Summary - CRP US on Roche / Hitachi Family of Clinical Analyzers

<b>Introduction</b>	According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence
<b>Submitter name, address, contact</b>	<p>Roche Diagnostics Corporation 9115 Hague Rd Indianapolis IN 46250 (317) 576 3723</p> <p>Contact person: Priscilla A Hamill</p> <p>Date prepared: October 27, 2000</p>
<b>Device Name</b>	<p>Proprietary name: CRP US Test System</p> <p>Common name: C-Reactive Protein test</p> <p>Classification name: System, Test, C-Reactive Protein</p>
<b>Device description</b>	The C-Reactive Protein US test is a latex particle-enhanced immunoturbidimetric assay packaged for use on the Roche/Hitachi family of analyzers.
<b>Intended use</b>	For the quantitative determination of C-reactive protein in human serum and plasma.
<b>Indication for use</b>	The C-reactive protein test is used for the detection and assessment of inflammatory disorders, tissue injury and infection.
<b>Substantial equivalence</b>	The CRP US test is equivalent to other devices legally marketed in the United States. We claim equivalence to the Roche Integra C-Reactive Protein test (K981897).

## 510(k) Summary - CRP US on Roche / Hitachi Family of Clinical Analyzers, continued

**Substantial  
equivalence -  
similarities**

The following table compares CRP US, with the predicate devices.

<b>Feature</b>	<b>New Device CRP US</b>	<b>Predicate Device Roche Integra Cassette (K981897)</b>
Intended use	For the quantitative determination of C-reactive protein	For the quantitative determination of C-reactive protein
Indication for use	Detection and assessment of inflammatory disorders, tissue injury and infection.	Detection and assessment of inflammatory disorders, tissue injury and infection.
Sample type	Human serum and plasma	Human serum and plasma
Traceability	IFCC/BCR/CAP reference preparation CRM 470 (RPPHS 91/0619)	IFCC/BCR/CAP reference preparation CRM 470 (RPPHS 91/0619)

**Substantial  
equivalence -  
differences**

The following table compares the CRP US, with the predicate devices.

<b>Feature</b>	<b>New Device CRP US</b>	<b>Predicate Device Roche Integra Cassette (K981897)</b>
Assay principle	Latex particle - enhanced immunoturbidimetric test	Latex particle - enhanced immunoturbidimetric test
Instrument	Roche/Hitachi family of analyzers	Integra family of analyzers

**Substantial  
equivalence -  
performance  
characteristics**

The performance characteristics of the CRP US were evaluated and found to be equivalent to those of the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAY 1 0 2001

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

Ms. Priscilla A. Hamill  
Regulatory Affairs, Laboratory Systems  
Roche Diagnostics Corporation  
9115 Hague Road  
P.O. Box 50457  
Indianapolis, IN 46250-0457

Re: 510(k) Number: K003400  
Trade/Device Name: CRP HS Test System  
Regulation Number: 866.5270  
Regulatory Class: II  
Product Code: DCN  
Dated: October 27, 2000  
Received: November 1, 2000

Dear Ms. Hamill:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

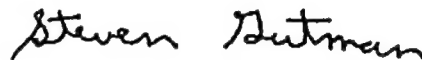
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive, flowing style.

Steven I. Gutman, M.D., M.B.A.  
Director  
Division of Clinical Laboratory Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

## INDICATIONS FOR USE STATEMENT

510(k) Number (if known): N/A K003400

Device Name: CRP US Test System

### Indications For Use:

For the quantitative determination of C-reactive protein in human serum and plasma. In acute phase response, increased levels of a number of plasma proteins, including C-reactive protein, are observed. Measurement of CRP is useful for the detection and evaluation of infection, tissue injury, inflammatory disorders, and associated diseases.

Fred Lacy

(Division Sign-Off)

Division of Clinical Laboratory Devices

510(k) Number K003400

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Concurrence of CDRH, Office of Device Evaluation (ODE)  
Prescription Use   /   OR Over-The-Counter Use             
(Per 21 CFR 801.109) (Optional Format 1-2-96)